1632

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/922,960
Filing Date	August 3, 2001
First Named Inventor	Michael Leviten
Art Unit	1632
Examiner Name	Valarie E. Bertoglio
Attorney Docket Number	R-441

Total Number of Pages in This Submission

ENCLOSURES (*Check all that apply*)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
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- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please Identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Aaron T. Hokamura, Reg. No. 51,810
Signature	
Date	February 12, 2002

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: February 12, 2002

Typed or printed	Don Mixon		
Signature		Date	February 12, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Michael W. LEVITEN

Group Art Unit: 1632

Serial No.: 09/922,960

Examiner: Bertoglio, Valarie E.

Filed: August 3, 2001

Attorney Docket No.: R-441

For: TRANSGENIC MICE CONTAINING UBIQUITIN PROTEIN LIGASE E3 GENE DISRUPTIONS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office communication mailed January 27, 2003, concerning the Examiner's restriction of the claims, Applicant hereby provisionally elects, with traverse, Group II (claims 5-10 and 17-24), drawn to a genetically modified animal cell, methods of using the cells to make a genetically modified non-human animal and a non-human transgenic animal.

In the restriction, the Examiner asserts that claims 1-29 are drawn to five distinct subjects, grouped as: Invention I (claims 1-4), drawn to a gene-targeting construct and a method of producing the gene-targeting construct; Invention II (claims 5-10 and 17-24), drawn to a genetically modified animal cell, methods of using the cells to make a genetically modified non-human animal, and a non-human transgenic animal; Invention III (claims 11, 12, 25 and 26), drawn to methods of using a non-human transgenic animal with a disruption in the ubiquitin ligase E3 gene to screen for agents that modulate ubiquitin ligase E3 expression or function; Invention IV (claims 13-15, 27 and 28), drawn to a method of identifying an agent that modulates ubiquitin ligase E3 expression or function by contacting the agent to a cell with a disruption in the ubiquitin ligase E3 gene; and Invention V (claims 16 and 29), drawn to an agent that modulates ubiquitin ligase E3 expression or function.

Specifically, the Examiner asserts that the claims of Invention I and Invention II are patentably distinct in that the nucleic acid construct of Invention I can be used as a probe while the cells of Invention II can be used in *in vitro* assays of ubiquitin ligase E3 function or to generate transgenic animals to be used as an animal model of disease. The Applicant disagrees with the

Examiner's conclusion. Applicant believes that a reasonable search or examination of the prior art would produce results related to the subject matter of both invention groups, and would not put serious burden on the Examiner.

The Examiner further asserts that the claims of Inventions I and Invention III or IV are patentably distinct because the construct can be used as a probe while the methods can be used to identify agents that modulate ubiquitin ligase E3 expression or function. The Applicant disagrees with the Examiner's assertion in that the construct of Invention I and the methods of invention III or IV are related and therefore a search or examination of these claims can be made without serious burden on the Examiner.

The Examiner also asserts that the claims of Invention I or II and Invention V are patentably distinct because the construct of Invention I and the cells and transgenic non-human animals of Invention II are not necessary for the agent and the agent is not needed for the nucleic acid, cells or animals. The Applicant disagrees with the Examiner's assertion in that the construct of Invention I and the cells and transgenic non-human animals of Invention II are related to the agent of Invention V and therefore, a search or examination of these claims would not unduly burden the Examiner.

Further, the Examiner asserts that the claims of Invention II and Invention III are related as product and process of use, and therefore distinct inventions. The Applicant disagrees with the Examiner's assertion. The claims of Inventions II and III are related. Thus, a search or examination of the prior art related to the subject matter of Invention II and Invention III would not place an undue burden on the Examiner.

The Examiner further asserts that the claims of Inventions II and IV are related as product and process of use, and therefore patentably distinct. The Examiner states that the cells and transgenic non-human animals of invention II can be used to determine the role of ubiquitin ligase E3. The Applicant disagrees with the Examiner's assertion in that the claims of Invention II are related to the claims of Invention IV, and therefore a search or examination of these claims would not unduly burden the Examiner.

It is further asserted by the Examiner that the methods of each of Inventions III and IV are materially different and plurally independent from each other because each is practiced with materially different process steps and technical consideration and requires materially distinct protocols and reagents. The Applicant disagrees with the Examiners assertion. The claims of Inventions III and IV are related. Therefore, a search or examination of these claims would not unduly burden the Examiner.

The Examiner further asserts that Invention III and Invention V are patentably distinct because the methods of Invention III can be used to identify modulators of ubiquitin ligase E3 expression or activity *in vivo*, while the agents of Invention V can be used to modulate ubiquitin ligase E3 expression or activity in cells. The Applicant disagrees with the Examiner in that the claims of Inventions III and V are related and therefore a search or examination would not seriously burden the Examiner.

The Examiner also asserts that Invention IV and Invention V are patentably distinct because the methods of Invention IV can be used to identify modulators of ubiquitin ligase E3 expression or activity *in vitro*, while the agents of Invention V can be used to treat disease symptom *in vivo*. The Applicant disagrees with the Examiners assertion. The claims of Inventions IV and V are related. Therefore, a search or examination of these claims would not unduly burden the Examiner.

Although Applicant has provisionally elected Group II for purposes of advancing prosecution of the present application, Applicant contends, for the foregoing reasons, that the restriction requirement is improper. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the requirement.

Respectfully submitted,

Date: January 12, 2005

Aaron T. Hokamura (Reg. No. 51,810)

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Enclosures

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,960	08/03/2001	Michael W. Leviten	R-441	9830

7590 01/27/2003

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EXAMINER
BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,960	LEVITEN, MICHAEL W.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30days* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a gene targeting construct and a method of producing the gene-targeting construct, classified in class 536, subclass 23.1.

II. Claims 5-10 and 17-24 , drawn to a genetically modified animal cell methods of using the cells to make a genetically modified non-human animal, and a non-human transgenic animal, classified in class 435; 800; 800, subclass 325;21;13.

III. Claims 11,12, 25, 26 drawn to methods of using a non-human, transgenic animal with a disruption in the ubiquitin ligase E3 gene to screen for agents that modulate the ubiquitin ligase E3 expression or function, classified in class 800, subclass 3.

IV. Claims 13,14,15, 27 and 28 drawn to a method of identifying an agent that modulates ubiquitin ligase E3 expression or function by contacting the agent to a cell with a disruption in the ubiquitin ligase E3 gene, classified in class 435, subclass 6.

V. Claims 16 and 29, drawn to an agent that is modulates ubiquitin ligase E3 expression or function, unclassifiable.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because, the nucleic acid construct can be used as probe while the cells can be used in in vitro assays of ubiquitin ligase E3 function or to generate transgenic animals to be used as an animal model of disease. The protocols and reagents required for the nucleic acid construct and the cells, methods of using the cells, and

the transgenic animal are materially distinct and separate. The burden required to search Inventions I and II together would be undue.

Inventions I and Invention III or IV are patentably distinct because the nucleic acid construct can be used as probe while the methods can be used to identify agents that modulate ubiquitin ligase E3 expression or function. The protocols and reagents required to make and use the nucleic acid construct are materially distinct from those for the methods of screening compounds. The burden required to search inventions I and III or IV together would be undue.

Inventions I or II and Invention V are patentably distinct because the nucleic acid construct of Invention I and the cells and transgenic non-human animals of Invention II are not necessary for the agent and the agent is not needed for nucleic acid, cells or animals. The protocols and reagents required for Inventions I and II are materially distinct from those for the agent of Invention V. The burden required to search Inventions I or II and Invention V together would be undue.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells and transgenic non-human animals of Invention II can be used to determine the role of ubiquitin ligase E3.

Inventions II and IV are related as product and process of use. In the instant case the cells and transgenic non-human animals of Invention II can be used to determine the role of ubiquitin ligase E3.

The methods of each of Inventions III and IV are materially different and plurally independent from each other because each is practiced with materially different process steps

and technical considerations and requires materially distinct protocols and reagents. Invention III uses a transgenic non-human animal. Invention IV uses cells, in vitro.

Invention III and V are patentably distinct because the methods of Invention III can be used to identify modulators of ubiquitin ligase E3 expression or activity in vivo while the agents of Invention V can be used to modulate ubiquitin ligase E3 expression or activity in cells. The methods are not necessary to make the agent. The burden required to search Invention III and V together would be undue.

Invention IV and V are patentably distinct because the methods of Invention IV can be used to identify modulators of ubiquitin ligase E3 expression or activity in vitro while the agents of Invention V can be used to treat disease symptoms in vivo. The methods are not necessary to make the agent. The burden required to search Invention IV and V together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the searches for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for

the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

Deborah Reynolds

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600